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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission: 22

Application Number	10/057,646
Filing Date	January 25, 2002
First Named Inventor	Harry R. Davis et al.
Art Unit	1617
Examiner Name	Shengjun Wang
Attorney Docket Number	CV01379K – 4686-045566

ENCLOSURES *(check all that apply)*

- [X] Fee Transmittal Form
  - [X] Fee Attached
- [ ] Amendment / Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
  - [ ] Response to Missing Parts Under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
  - [ ] Landscape Table on CD
- [ ] After Allowance communication to TC
- [ ] Appeal Communication to Board of Appeals and Interferences
- [X] Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
- [ ] Status Letter
- [ ] Other Enclosure(s) (please identify below):

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	The Webb Law Firm		
Signature			
Printed Name	Ann M. Cannoni		
Date	September 20, 2005	Reg. No.	35,972

CERTIFICATE OF TRANSMISSION / MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as Express mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	Chris Craig		
Typed or printed name	Chris Craig	Date	September 20, 2005

PTO/SB/17 (12-04)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818)

FEE TRANSMITTAL For FY 2005

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT	($) 500.00

Complete if Known	
Application Number	10/057,646
Filing Date	January 25, 2002
First Named Inventor	Harry R. Davis, et al.
Examiner Name	Shengjun Wang
Art Unit	1617
Attorney Docket No.	CV01379K/4686-045566

METHOD OF PAYMENT (check all that apply)

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☐ Deposit Account Deposit Account Number: 23-0650 Deposit Account Name The Webb Law Firm

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FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
		Small Entity		Small Entity		Small Entity	
Application Type	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fees Paid ($)
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent	50	25
Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent	200	100
Multiple dependent claims	360	180

Total Claims		Extra Claims		Fee ($)		Fee Paid ($)
_____	- 20 or HP =	_____	x	_____	=	_____

HP = highest number of total claims paid for, if greater than 20

Multiple Dependent Claims	
Fee ($)	Fee Paid ($)
_____	_____

Indep. Claims		Extra Claims		Fee ($)		Fee Paid ($)
_____	- 3 or HP =	_____	x	_____	=	_____

HP = highest number of independent claims paid for, if greater than 3

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets		Extra Sheets		Number of each additional 50 or fraction thereof		Fee ($)		Fee Paid ($)
_____	- 100 =	_____	/ 50 =	_____	(round **up** to a whole number) x	_____	=	_____

4. OTHER FEE(S)

	Fee Paid ($)
Non-English Specification, $130 fee (no small entity discount)	
Other: Appeal Brief	500.00

SUBMITTED BY

Signature		Registration No. (Attorney/Agent) 35,972	Telephone 412-471-8815
Name (Print/Type)	Ann M. Cannoni		Date September 20, 2005

Response Under 37 C.F.R. §1.192
Appellant's Brief

Application No. 10/057,646
Paper Dated: September 20, 2005
Attorney Docket No. CV01379K

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re:	Patent Application of Harry R. Davis et al.	: PATENT APPLICATION
Serial No.:	10/057,646	: Group Art Unit: 1617
Filed:	January 25, 2002	: Examiner: Shengjun Wang
For:	Combinations of Nicotinic Acid and Derivatives Thereof and Sterol Absorption Inhibitor(s) and Treatments for Vascular Indications	: Atty. Docket No.: CV01379K

MAIL STOP APPEAL BRIEF – PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

ON APPEAL FROM THE PRIMARY EXAMINER TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

APPELLANT'S BRIEF UNDER 37 C.F.R. § 1.192

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as Express Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

September 20, 2005 Chris Craig
Date Signature

Chris Craig
Typed Name of Person Signing Certificate

09/22/2005 WABDELR1 00000031 10057646 500.00 OP
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TABLE OF CONTENTS

I

REAL PARTY IN INTEREST

The real party in interest in this Appeal is assignee Schering Corporation, having a principal place of business 2000 Galloping Hill Road, Kenilworth, NJ 07033.

II

RELATED APPEALS AND INTERFERENCES

As the legal representative of Appellant, the undersigned attorney has no knowledge of any appeals or interferences directly related to this Appeal.

III

STATUS OF CLAIMS

This is an original patent application in which claims 1-4, 7-10, 28-30 and 32 are pending in the application. Claims 11-27, 36-39, 41, 44-46, 51, 54, 56, 59, 61, 64, 66, 69, 72, 75, 78 and 81 have been withdrawn from consideration by the Examiner as being non-elected. Claims 5, 6, 31 and 33-81 were previously canceled without prejudice to filing one or more divisional applications directed to the subject matter thereof.

Claims 1-4, 7-10, 28-30 and 32 (pending) were finally rejected under 35 U.S.C. §103(a) in an Office Action mailed March 24, 2005 ("Final Office Action") and Advisory Action mailed June 15, 2005 ("Advisory Action").

Twelve (12) pending claims (1-4, 7-10, 28-30 and 32) are at issue in this Appeal.

IV

STATUS OF AMENDMENTS

No claims were amended after final rejection. A copy of the claims involved in this Appeal is contained in the Appendix attached hereto.

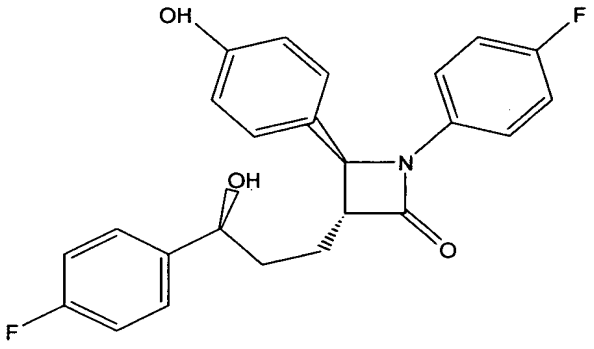
V

SUMMARY OF CLAIMED SUBJECT MATTER

In embodiments set forth in claim 1, Applicants have discovered compositions comprising:

(a) at least one of nicotinic acid or derivatives thereof; and

(b) 10 milligrams of a sterol absorption inhibitor represented by Formula (II):



(II)

or a pharmaceutically acceptable salt or solvate thereof.

See original claims 1 and 5, and page 80 of the specification.

In other embodiments set forth in Claim 32, Applicants have discovered therapeutic combinations comprising:

(a) a first amount of at least one of nicotinic acid or derivatives thereof; and

(b) a second amount of 10 milligrams of a compound represented by Formula (II) or pharmaceutically acceptable salt or solvate thereof, wherein the first amount and the second amount together comprise a therapeutically effective amount for the treatment or prevention of a vascular condition, diabetes, obesity or lowering a concentration of a sterol in plasma of a mammal.

The compound of Formula (II) above is ezetimibe, which is the active ingredient in ZETIA™ (ezetimibe) pharmaceutical formulation and VYTORIN™ (ezetimibe/simvastatin) pharmaceutical formulation, both of which are

commercially available from MSP (Merck Schering-Plough) Pharmaceuticals, Inc. See Response to Restriction Requirement and Election of Species of ("Restriction and Election Response") at page 2, lines 8-9.

Applicants provisionally elected with traverse nicotinic acid as the species of nicotinic acid or derivatives thereof for initial examination in the application. See Restriction and Election Response at page 2, lines 6-7.

The claimed compositions and combinations can be useful for treating or preventing a vascular condition, diabetes, obesity and/or lowering concentration of a sterol or 5α-stanol in plasma in a subject. See page 81, lines 1-11 of the specification.

VI

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

I. Has a Prima Facie Case of Obviousness Under 35 U.S.C. § 103 Over Claims 1-3, 5-28, 31-36, 70-72, 74-77, 79 and 80 as obvious over U.S. Patent No. 5,846,966 ("Rosenblum et al.") in view of U.S Patent No. 5,698,527 ("Kim") and WO 2000/38725 ("Keller et al.") Been Established?

VII

ARGUMENT

I. The Required Prima Facie Case of Obviousness of Claims 1-3, 5-28, 31-36, 70-72, 74-77, 79 and 80 Under 35 U.S.C. § 103 Over U.S. Patent No. 5,846,966 ("Rosenblum et al.") in view of U.S Patent No. 5,698,527 ("Kim") and WO 2000/38725 ("Keller et al.") has Failed to be Established.

A. The Rejection

Claims 1-4, 7-10, 28-30 and 32 have been rejected as obvious over U.S. Patent No. 5,846,966 ("Rosenblum et al.") in view of U.S Patent No. 5,698,527 ("Kim") and WO 2000/38725 ("Keller et al.").

The reasons for rejection are set forth in the Final Office Action, summarized as follows:

It is asserted that Rosenblum et al. teach the instant cholesterol absorption inhibitors, their application for lowering serum cholesterol and combination with other cholesterol lowering agents such as simvastatin. Final Office Action at page 2. Further, it is asserted that Rosenblum et al, teach a daily dosage in a range of 5 mg to 1000 mg a dose given 1 or two times a day

and that the exact dose would depend upon various conditions. Final Office Action at page 2.

It is acknowledged that Rosenblum et al. do not expressly teach a combination of a cholesterol absorption inhibitor, such as ezetimibe, and a nicotinic acid. Final Office Action at page 3.

In the rejection, it is alleged that Kim teaches that niacin is a well-known cholesterol lowering agent and is particularly useful in combination with cholesterol absorption inhibitors. Final Office Action at page 3. It is further alleged that Keller et al. teach various combinations of cholesterol lowering agents, including ezetimibe and nicotinic acid, for treating hypercholesterolemia-associated disorders. Final Office Action at page 3.

It is alleged that it would have been obvious to one of ordinary skill in the art, at the time that the claimed invention was made, to make a composition comprising ezetimibe and nicotinic acid, and optionally simvastatin, citing In re Kerkoven, 205 U.S.P.Q. 1069. Final Office Action at page 3.

It is further alleged that the specific amount of 10 mg is within the range disclosed by Rosenblum et al. Final Office Action at page 3.

B. The Prior Art

Rosenblum et al. disclose cholesterol absorption inhibitors, their application for lowering serum cholesterol and combination with simvastatin. Rosenblum et al. do not teach a combination of a cholesterol absorption inhibitor, such as ezetimibe, and nicotinic acid, or in further combination with a cholesterol biosynthesis inhibitor, e.g. simvastatin.

Kim discloses steroidal glycoside cholesterol absorption inhibitors that can be administered in combination with niacin, but does not suggest or disclose combining ezetimibe with niacin or the desirability of the claimed amount of 10 milligrams of ezetimibe. Ezetimibe is not a steroidal glycoside.

Keller et al. disclose combinations of (1) an ileal bile acid transport

inhibitor or CETP inhibitor and (2) a cholesterol absorption inhibitor such as ezetimibe, but not the combination of ezetimibe and nicotinic acid.

C. The Required Prima Facie Case of Obviousness Under 35 U.S.C. § 103 Has Not Been Established

The law is replete with cases holding that there must be some suggestion or motivation in the prior art to combine the references. When making a rejection under 35 U.S.C. § 103, the Examiner has the burden of establishing a prima facie case of obviousness. In re Fritch, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992).

The Examiner can satisfy this burden only by showing an objective teaching in the prior art, or knowledge generally available to one of ordinary skill in the art, which would lead an individual to combine the relevant teachings of the references [and/or the knowledge] in the manner suggested by the Examiner. Id.; In re Fine, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988).

The mere fact that the prior art could be modified does not make the modification obvious *unless the prior art suggests the desirability of the modification* (emphasis added). In re Fritch, 23 U.S.P.Q.2d at 1784; In re Laskowski, 10 U.S.P.Q.2d 1397, 1398 (Fed. Cir. 1989); In re Gordon, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984).

"The ultimate determination of patentability must be based on consideration of the entire record, by a preponderance of evidence, with due consideration to the persuasiveness of any arguments and any secondary evidence." Manual of Patent Examining Procedure, (Rev. 1, Feb. 2003) § 716.01(d) and In re Oetiker, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992).

Claims 1-4, 7-10, 28-30 and 32

Claims 1 and 32 recite a composition and therapeutic combination, respectively, comprising: (a) at least one nicotinic acid or derivative thereof; and (b) about 10 milligrams of at least one sterol absorption inhibitor represented by Formula (II) above.

Claim 2 depends from claim 1 and further recites that the at least one of nicotinic acid or derivatives thereof is selected from the group consisting of nicotinic acid, niceritrol, nicofuranose, acipimox and mixtures thereof.

Claim 3 depends from claim 2 and further recites that the at least one of nicotinic acid or derivatives thereof is nicotinic acid.

Claim 4 depends from claim 1 and further recites that the at least one of nicotinic acid or derivatives thereof is administered to a mammal in an amount ranging from about 500 to about 10,000 milligrams of nicotinic acid or derivatives thereof per day.

Claim 7 depends from claim 1 and further recites that the composition further comprises at least one cholesterol biosynthesis inhibitor.

Claim 8 depends from claim 7 and further recites that the at least one cholesterol biosynthesis inhibitor comprises at least one HMG CoA reductase inhibitor.

Claim 9 depends from claim 8 and further recites that the at least one HMG CoA reductase inhibitor is selected from the group consisting of lovastatin, pravastatin, fluvastatin, simvastatin, atorvastatin, cerivastatin and mixtures thereof.

Claim 10 depends from claim 9 and further recites that the at least one HMG CoA reductase inhibitor is simvastatin.

Claim 28 depends from claim 1 and recites a pharmaceutical composition for the treatment or prevention of a vascular condition, diabetes, obesity or lowering a concentration of a sterol in plasma of a mammal, comprising a therapeutically effective amount of the composition of claim 1 and a pharmaceutically acceptable carrier.

Claim 29 depends from claim 1 and recites a method of treating or preventing a vascular condition, diabetes, obesity or lowering a concentration of a sterol in plasma of a mammal, comprising the step of administering to a mammal in need of such treatment an effective amount of the composition of claim 1.

Claim 30 depends from claim 29 and further recites that the vascular condition is hyperlipidemia.

As shown in Table 1 of the present application, Compound XII (a substituted azetidinone cholesterol absorption inhibitor) reduced plasma cholesterol levels and the accumulation of hepatic cholesteryl esters in the cholesterol-fed hamsters. Niacin reduced plasma triglyceride levels, but did not significantly reduce the cholesterol levels. The combination of Compound XII and niacin resulted in reductions in plasma and hepatic cholesterol levels, as well as plasma triglycerides (Table 1). These results indicate that the combination of the cholesterol absorption inhibitor of Compound XII and niacin can have additive effects on treating hyperlipidemia in male Golden Syrian hamsters, by reducing both cholesterol and triglyceride levels. One skilled in the art would understand that the compatibility and efficacy of drug combinations can be unpredictable.

Rosenblum et al. do not suggest or disclose the combination of ezetimibe and nicotinic acid. Rosenblum et al. do not suggest or disclose the

desirability of a 10 milligram dosage of ezetimibe. Rosenblum et al. do not suggest or disclose lowering of triglyceride levels.

Kim discloses steroidal glycoside cholesterol absorption inhibitors that can be administered in combination with niacin, but does not suggest or disclose combining ezetimibe with niacin or the desirability of the claimed amount of 10 milligrams of ezetimibe. Ezetimibe is not a steroidal glycoside. The steroidal glycosides disclosed by Kim are structurally very dissimilar to the presently claimed substituted azetidinone compound ezetimibe. Given their large molecular size, it is unlikely that Kim's steroidal glycosides are absorbed through the intestine. In contrast, multiple peaks in plasma concentration-time profiles suggest that the glucuronide conjugate of ezetimibe undergoes enterohepatic recycling before elimination. See ZETIA™ (ezetimibe) Tablets Package Insert at column 2 (Merck/Schering-Plough Pharmaceuticals) (October 2002), included in the Information Disclosure Statement of August 30, 2004. This enterohepatic recycling can enhance efficacy. It would not be obvious to one of ordinary skill in the art to substitute ezetimibe disclosed by Rosenblum et al. for the steroidal glycosides disclosed by Kim, since they are likely to be dissimilar in site of action.

Kim's steroidal glycoside compounds have not been commercialized by Merck & Co., Inc. (the assignee of the Kim patent). Rather, Merck is the joint venture partner of Schering-Plough (assignee of the present application) in marketing the cholesterol absorption inhibitor ZETIA™ ezetimibe formulation. ZETIA was launched in late 2002 and global sales of ZETIA in the 2003 fourth

quarter totaled $165 million, with U.S. sales of $144 million. Press Release: Schering-Plough Reports Financial Results for 2003 Fourth Quarter, Full Year (Monday January 26, 6:33 am ET). Thus it can be inferred that Kim's steroidal glycoside compounds, administered alone or in combination with niacin, were not commercially viable as treatments.

"[S]econdary considerations such as ... commercial success, long-felt need, failure of others ... are relevant to the issue of obviousness and must be considered in every case in which they are present. When evidence of any of these secondary considerations is submitted, the examiner must evaluate the evidence." M.P.E.P. § 2141 (Rev'd May 2004). Applicants respectfully request that the above information regarding commercial success, long-felt need, and failure of others be considered by the Examiner.

No data is presented in the Kim reference to support efficacy of a combination of steroidal glycoside and niacin. One skilled in the art would not be motivated to combine ezetimibe and nicotinic acid based upon the disclosure of Kim since the steroidal glycoside and ezetimibe molecules are so structurally dissimilar.

Keller et al. disclose combinations of (1) an ileal bile acid transport inhibitor or CETP inhibitor and (2) a cholesterol absorption inhibitor such as ezetimibe, but *not the combination of ezetimibe and nicotinic acid.* Also, Keller does not suggest or disclose the desirability of a 10 mg dosage of ezetimibe.

It is respectfully submitted that the combination of the references cited as rendering the claimed invention obvious is improper because there is no

suggestion in any of the cited references, taken alone or combined as advocated in the rejection, to combine the claimed components of 10 milligrams of ezetimibe and nicotinic acid.

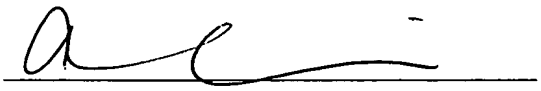
Even if the teachings of the references were combined as set forth in the Office Action, there are not sufficient teachings to motivate one of ordinary skill in the art to pick and choose among thousands of compounds to combine 10 milligrams of ezetimibe with nicotinic acid.

Neither Rosenblum et al, Kim, nor Keller et al., taken alone or combined as set forth in the Office Action, provides motivation for combining 10 milligrams of ezetimibe and niacin. Also, Applicants respectfully request that the above information regarding commercial success, long-felt need, failure of others be considered by the Examiner.

Applicants respectfully assert that the rejection is based upon improper hindsight reconstruction. The prima facie case of obviousness has not been established. Accordingly, Applicants respectfully request that the § 103(a) rejection of claims 1-4, 7-10, 28-30 and 32 be reconsidered and withdrawn.

Respectfully submitted,

Date: September 20, 2005



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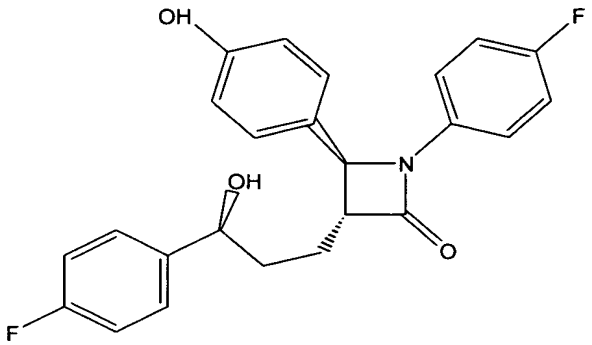
CLAIM APPENDIX

1. A composition comprising:

(a) at least one of nicotinic acid or derivatives thereof; and

(b) 10 milligrams of a sterol absorption inhibitor represented by Formula (II):



(II)

or a pharmaceutically acceptable salt or solvate thereof.

2. The composition according to claim 1, wherein the at least one of nicotinic acid or derivatives thereof is selected from the group consisting of nicotinic acid, niceritrol, nicofuranose, acipimox and mixtures thereof.

3. The composition according to claim 2, wherein the at least one of nicotinic acid or derivatives thereof is nicotinic acid.

4. The composition according to claim 1, wherein the at least one of nicotinic acid or derivatives thereof is administered to a mammal in an amount ranging from about 500 to about 10,000 milligrams of nicotinic acid or derivatives thereof per day.

7. The composition according to claim 1, further comprising at least one cholesterol biosynthesis inhibitor.

8. The composition according to claim 7, wherein the at least one cholesterol biosynthesis inhibitor comprises at least one HMG CoA reductase inhibitor.

9. The composition according to claim 8, wherein the at least one HMG CoA reductase inhibitor is selected from the group consisting of lovastatin, pravastatin, fluvastatin, simvastatin, atorvastatin, cerivastatin and mixtures thereof.

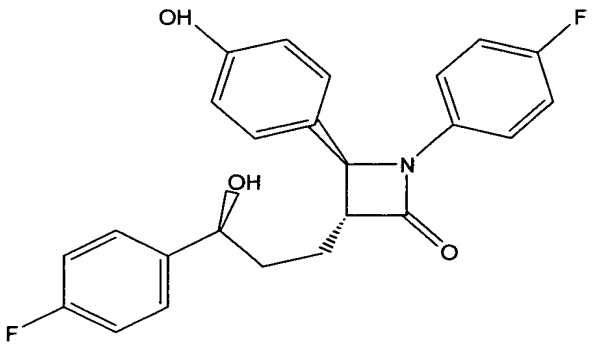
10. The composition according to claim 9, wherein the at least one HMG CoA reductase inhibitor is simvastatin.

28. A pharmaceutical composition for the treatment or prevention of a vascular condition, diabetes, obesity or lowering a concentration of a sterol in plasma of a mammal, comprising a therapeutically effective amount of the composition of claim 1 and a pharmaceutically acceptable carrier.

29. A method of treating or preventing a vascular condition, diabetes, obesity or lowering a concentration of a sterol in plasma of a mammal, comprising the step of administering to a mammal in need of such treatment an effective amount of the composition of claim 1.

30. The method according to claim 29, wherein the vascular condition is hyperlipidemia.

32. A therapeutic combination comprising: (a) a first amount of at least one of nicotinic acid or derivatives thereof; and (b) a second amount of 10 milligrams of a compound represented by Formula (II) below:



(II)

or pharmaceutically acceptable salt or solvate thereof, wherein the first amount and the second amount together comprise a therapeutically effective amount for the treatment or prevention of a vascular condition, diabetes, obesity or lowering a concentration of a sterol in plasma of a mammal.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.